

PATENT

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Michelle Hobson
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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Application of:

MILLER et al.

Application No.: 10/587,723

International Appl. No. PCT/US2005/003245

International Filing Date: February 3, 2005

Title: METHODS AND COMPOSITIONS FOR
TARGETED CLEAVAGE AND RECOMBINATION

Examiner:

Group Art Unit:

Confirmation No.: 2253

Customer No.: 20855

**INFORMATION DISCLOSURE STATEMENT
UNDER 37 C.F.R. §1.97(b)**

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sirs:

In accordance with the duty of disclosure set forth in 37 C.F.R. §1.56,
Applicant(s) hereby submits the following information in conformance with 37 C.F.R.
§§1.97 and 1.98.

- ☐ Pursuant to 37 C.F.R. §1.98, copies of publication _____ cited in the attached Form PTO/SB/08 are enclosed.
- ☒ No copies of the U.S. publications A1-A35 listed on the attached Form PTO/SB/08A are being provided because the Office waives the requirement under 37 C.F.R. 1.98 (a) (2) (i) for submitting a copy of each cited U.S. patent and each U. S. patent application publication for all U.S. national patent applications filed after June 30, 2003.
- ☒ No copies of the publications B1-B20 and C1-C102 on the attached Form PTO/SB/08A are being provided pursuant to 37 C.F.R. §1.98(d) because the publications were previously cited by or submitted to the Office in

prior Application Serial No. 10/912,932 to which the above-identified application claims priority under 35 U.S.C. §120.

- ☐ Publication(s) _____ listed on the attached Form PTO/SB/08A were cited in a foreign search or examination report corresponding to PCT application serial no. _____ and mailed on _____.
- ☐ Enclosed is a copy of a non-English publication(s) _____. Pursuant to §609 of the M.P.E.P., Applicant submits the attached foreign search or examination report, which cites such non-English language publication(s).
- ☐ Enclosed is a copy of a non-English publication(s) _____. English language publication _____ (copy enclosed) claims priority from this non-English publication.
- ☐ Enclosed is an explanation of non-English publication(s) _____ for which an English translation is not available.
- ☐ Enclosed is an English translation of non-English publication(s) _____ cited in the attached Form PTO/SB/08A.
- ☐ Enclosed is a copy of pending patent Application Serial No. _____.

This Information Disclosure Statement is filed within any one of the following time periods:

- ☐ within three months from the filing date of this national application other than a CPA under 37 C.F.R. § 1.53(d);
- ☐ within three months from the date of entry of the national stage as set forth in 37 C.F.R. §1.491 in this international application;
- ☒ before the mailing date of a first office action on the merits; or
- ☐ before the mailing of a first office action after the filing of a request for continued examination under 37 C.F.R. §1.114.


This Information Disclosure Statement under 37 CFR § 1.97 is not to be construed as a representation that: (i) a complete search has been made; (ii) additional information material to the examination of this application does not exist; (iii) the information, protocols, results and the like reported by third parties are accurate or enabling; or (iv) the above information constitutes prior art to the subject invention.

It is respectfully requested that the Examiner consider the above-noted information and return an initialed copy of the attached Form PTO/SB/08A to the undersigned.

Respectfully submitted,

Date: April 25, 2007

By:


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Substitute for form 1449A/PTO

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

(use as many sheets as necessary)

Complete if Known

Sheet	2	of	10	Application Number	10/587,723
				Filing Date	February 3, 2005
				First Named Inventor	MILLER et al.
				Group Art Unit	
				Examiner Name	
				Attorney Docket Number	8325-0036.31 (S36-US3)

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	Foreign Patent Document			Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	T ³
		Office ³	Number ⁴	Kind Code			
	B1	WO	95/09233		Johns Hopkins University	04-06-1995	
	B2	WO	96/40882		Ohio State University	12-19-1996	
	B3	WO	97/47758		MIT, Einstein Coll. Med.	12-18-1997	
	B4	WO	98/53058		Med. Res. Council	11-26-1998	
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	B7	WO	00/09755		Pangene Corporation	02-24-2000	
	B8	WO	00/28008		Maxygen, Inc.	05-18-2000	
	B9	WO	00/42219		Sangamo BioSciences, Inc.	07-20-2000	
	B10	WO	00/46385		Child. Med. Cntr	08-10-2000	
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	B17	WO	02/04488		Sangamo BioSciences, Inc.	01-17-2002	
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	B19	WO	03/087341		Univ. of Utah	10-23-2003	
	B20	EP	0 957 165		Roche	11-17-1999	

OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ¹
	C1	Aggarwal, et al., "Novel Site-Specific DNA Endonucleases," <i>Current Opinion in Structural Biology</i> 8:19-25 (1998)	
	C2	Abrenski, et al., "Bacteriophage P1 Site Specific Recombination," <i>J. Biol. Chem.</i> 259:1509-1514 (1984)	
	C3	Akopian, et al., "Chimeric Recombinases with Designed DNA Sequence Recognition," <i>Proc. Natl. Acad. Sci. USA</i> 100:8688-8691 (2003)	
	C4	Baubonis, et al., "Genomic Targeting with Purified Cre Recombinase," <i>Nucleic Acids Res.</i> 21:2025-2029 (1993)	

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³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3).

⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document.

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C5	Beerli, et al., "Engineering Polydactyl Zinc-Finger Transcription Factors," <i>Nature Biotechnology</i> <u>20</u> :135-141 (2000)	
C6	Bibikova, et al., "Stimulation of Homologous Recombination through Targeted Cleavage by Chimeric Nucleases," <i>Molecular and Cellular Biology</i> <u>21</u> (1):289-297 (2001)	
C7	Bibikova, et al., "Targeted Chromosomal Cleavage and Mutagenesis in Drosophila Using Zinc-Finger Nucleases," <i>Genetics</i> <u>161</u> :1169-1175 (2002)	
C8	Bibikova, et al., "Enhancing Gene Targeting with Designed Zinc Finger Nucleases," <i>Science</i> <u>300</u> :764 (2003) INCLUDING SUPPORTING ONLINE MATERIALS	
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C14	Cappechi, et al., "Altering the Genome by Homologous Recombination," <i>Science</i> <u>244</u> :1288-1292 (1989)	
C15	Chandrasegaran, et al., "Chimeric Restriction Enzymes: What is Next?" <i>Biol Chem.</i> <u>280</u> :841-848 (1999)	
C16	Chevalier, et al., "Design, Activity, and Structure of a Highly Specific Artificial Endonuclease," <i>Molecular Cell</i> <u>10</u> :895-905 (2002)	
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Sheet	4	of	10	Attorney Docket Number 8325-0036.31 (S36-US3)

C18	Cohen-Tannoudji, et al., "1-Scel-Induced Gene Replacement at a Natural Locus in Embryonic Stem Cells," <i>Molecular and Cellular Biology</i> 18(3):1444-1448 (1998)	
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C20	Desjarlais, et al., "Use of a Zinc-Finger Consensus Sequence Framework and Specificity Rules to Design Specific DNA Binding Proteins," <i>Proc. Natl. Acad. Sci. USA</i> 90:2256-2260 (1993)	
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C25	Elliott, et al., "Gene Conversion Tracts from Double Strand Break Repair in Mammalian Cells," <i>Molecular and Cellular Biology</i> 18(1):93-101 (1998)	
C26	Elrod-Erickson, et al., "Binding Studies with Mutants of Zif268," <i>J. Biol. Chem.</i> 274(27):19281-19285 (1999)	
C27	Evans, et al., Establishment in Culture of Pluripotential Cells from Mouse Embryos," <i>Nature</i> 292:154-156 (1981)	
C28	Ferguson-Smith, "Imprinting and the Epigenetic Asymmetry Between Parental Genomes," <i>Science</i> 293:1086-1089 (2001)	
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C30	Greisman, et al., "A General Strategy for Selecting High-Affinity Zinc Finger Proteins for Diverse DNA Target Sites," <i>Science</i> 275:657-661 (1997)	

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C31	Gowda, et al., "Identification of Promoter Sequences for the Major RNA Transcripts of Figwort Mosaic and Peanut Chlorotic Streak Virus (Caulimovirus Group)," <i>J. Cell. Biochem.</i> <u>13D</u> :301 (1989)	
C32	Gu, et al., "Independent Control of Immunoglobulin Switch Recombination at Individual Switch Regions Evidenced through Cre-loxP-Mediated Gene Targeting," <i>Cell</i> <u>73</u> :1155-1164 (1993)	
C33	Gu, et al., "Deletion of a DNA Polymerase B Gene Segment in T Cells Using Cell Type-Specific Gene Targeting," <i>Science</i> <u>265</u> :103-106 (1994)	
C34	Gurley, et al., "Upstream Sequences Required for Efficient Expression of a Soybean Heat Shock Gene," <i>Mol. Cell. Biol.</i> <u>6</u> :559-565 (1986)	
C35	Hanson, et al., "Analysis of Biological Selections for High-Efficiency Gene Targeting," <i>Mol. Cell. Biol.</i> <u>15</u> :45-51 (1995)	
C36	Hicks, et al., "Three Classes of Nuclear Import Signals Bind to Plant Nuclei," <i>Plant Physiol.</i> <u>107</u> :1055-1058 (1995)	
C37	Huang, et al., "Splase: A New Class IIS Zinc-Finger Restriction Endonuclease with Specificity for Sp1 Binding Sites," <i>Journal of Protein Chemistry</i> <u>15</u> (5):481-489 (1996)	
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C39	Jaenisch, "Transgenic Animals," <i>Science</i> <u>240</u> :1468-1474 (1988)	
C40	Jasin, "Genetic Manipulation of Genomes with Rare-Cutting Endonucleases," <i>Trends Genet.</i> <u>12</u> :224-228 (1996)	
C41	Jeggio, et al., "Identification of Genes Involved in Repair of Dna Double-Strand Breaks in Mammalian Cells," <i>Radiation Research</i> <u>150</u> :S80-S91 (1998)	
C42	Johnson, et al., "Double-Strand-Break-Induced Homologous Recombination in Mammalian Cells," <i>Biochemical Society Transactions</i> <u>29</u> :196-201 (2001)	
C43	Khanna, et al., "DNA Double-Strand Breaks: Signaling, Repair and the Cancer Connection," <i>Nature Genetics</i> <u>27</u> :247-254 (2001)	

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C44	Kim, <i>et al.</i> , "Construction of a Z-Dna-Specific Restriction Endonuclease," <i>Proc. Natl. Acad. Sci. USA</i> <u>94</u> :12875-12879 (1997)	
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C46	Kim, <i>et al.</i> , "Chimeric Restriction Endonuclease," <i>Proc. Natl. Acad. Sci. USA</i> <u>91</u> :883-887 (1994)	
C47	Kim, <i>et al.</i> , "Chimeric Restriction Enzyme: Gal4 Fusion to FokI Cleavage Domain," <i>Biol. Chem.</i> <u>379</u> :489-495 (1998)	
C48	Kim, <i>et al.</i> , "Insertion and Deletion of Mutants of FokI Restriction Endonuclease," <i>Journal of Biol. Chem.</i> <u>269</u> (50):31978-31982 (1994)	
C49	Klein, <i>et al.</i> , "Transformation of Microbes, Plants and Animals by Particle Bombardment," <i>Bio/Techniques</i> <u>10</u> :286-291 (1992)	
C50	Klein, <i>et al.</i> , "High-Velocity Microprojectiles for Delivering Nucleic Acids into Living Cells," <i>Nature</i> <u>327</u> :70-73 (1987)	
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C55	Liu, <i>et al.</i> , "Validated Zinc Finger Protein Designs for All 16 GNN DNA Triplet Targets," <i>J. Biol. Chem.</i> <u>277</u> (6):3850-3856 (2002)	
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C57	Mattaj, et al., "Nucleocytoplasmic Transport: The Soluble Phase," <i>Annu. Rev. Biochem.</i> <u>67</u> :265-306 (1998)	
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C62	Palu, et al., "In pursuit of new developments for gene therapy of human diseases," <i>J. Biotechnol</i> <u>68</u> :1-13 (1999)	
C63	Porteus, et al., "Efficient Gene Targeting Mediated by Adeno-Associated Virus and DNA Double-Strand Breaks," <i>Mol. Cell. Biol.</i> <u>23</u> :3558-3565 (2003)	
C64	Porteus, et al., "Chimeric Nucleases Stimulate Gene Targeting in Human Cells," <i>Science</i> <u>300</u> :763 (2003) INCLUDING SUPPORTING ONLINE MATERIALS	
C65	Puchta, et al., "Homologous Recombination in Plant Cells is Enhanced by In Vivo Induction of Double Strand Breaks into DNA by a Site-Specific Endonuclease," <i>Nucleic Acids Res.</i> <u>21</u> :5034-5040 (1993)	
C66	Rebar, et al., "Zinc Finger Phage: Affinity Selection of Fingers with New DNA-Binding Specificities," <i>Science</i> <u>263</u> :671-673 (1994)	
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C70	Sanford, <i>et al.</i> , "An Improved, Helium-Driven Biolistic Device," <i>Tech.-A J. of Meth. In Cell and Mol. Biol.</i> 3:3-16 (1991)	
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C73	Schnieke, <i>et al.</i> , "Human Factor IX Transgenic Sheep Produced by Transfer of Nuclei from Transfected Fetal Fibroblasts," <i>Science</i> 278:2130-2133 (1997)	
C74	Sedivy, <i>et al.</i> , "Positive Genetic Selection for Gene Disruption in Mammalian Cells by Homologous Recombination," <i>Proc. Natl. Acad. Sci. USA</i> 86:227-231 (1989)	
C75	Segal, <i>et al.</i> , "Endonuclease-Induced, Targeted Homologous Extrachromosomal Recombination in <i>Xenopus</i> Oocytes," <i>Proc. Natl. Acad. Sci. USA</i> 92:806-810 (1995)	
C76	Segal, <i>et al.</i> , "Toward Controlling Gene Expression at Will: Selection and Design of Zinc Finger Domains Recognizing Each of the 5'-GNN-3' DNA Target Sequences," <i>Proc. Natl. Acad. Sci. USA</i> 96:2758-2763 (1999)	
C77	Segal, D. J., "The Use of Zinc Finger Peptides to Study the Role of the Specific factor Binding Sites in the Chromatin Environment," <i>Methods</i> 26:76-83 (2002)	
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		Application Number	10/587,723
		Filing Date	February 3, 2005
		First Named Inventor	MILLER et al.
		Group Art Unit	
Examiner Name			
Attorney Docket Number	8325-0036.31 (S36-US3)		
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C83	Smith, et al., "Double Strand Breaks at the target Locus Stimulate Gene targeting in Embryonic Stem Cells," <i>Nuc. Acids Res.</i> 23 (24):5012-5019 (1995)	
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PTO/SB/08A (08-00)

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C96	Wilmot, et al., "Viable Offspring Derived from Fetal and Adult Mammalian Cells," <i>Nature</i> <u>385</u> :810-813 (1997)	
C97	Wilson, J. H., "Pointing Fingers at the Limiting Step in Gene targeting," <i>Nature Biotechnology</i> <u>21</u> (7):759-760 (2003)	
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